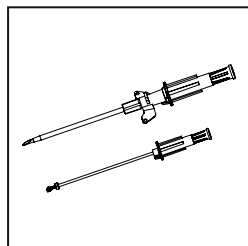




PLUSKI SAFE®

Safety I.V. Cannula

Without Injection Valve With Small Wings



SRN. No: IN-MF-000007279

Basic UDI-DI #: 890602530SAFIVCANNULAXM



INSTRUCTIONS FOR USE

Materials Used: PTFE/FEP/PUR (Radio-Opaque strip/Natural), PP, POM, K-Resin & Stainless Steel.

Device General Description: A sterile, thin, flexible tube intended to be inserted into the peripheral vasculature of a patient to enable short-term intravascular access; it is not intended to be advanced to the central vasculature. It typically includes dedicated accessories to facilitate catheter introduction/placement and function. It may be used for blood sampling, to administer fluids, medication and/or for the injection of contrast media. This is a sterile single-use device.

Intended Purpose/Use: The I.V. Cannula is used for access to the human circulatory system for introduction of fluids or medication and/or withdrawal of blood samples. It provides a closed path system of fluid container & patient.

Intended Users: Uses is restricted to a qualified Doctor or a Paramedic.

Principle of Operation: At the time of venipuncture the angle of entry into the vein depends on the depth of the vein and the chosen site, this is approximately 20-30 degrees. The bevel of the needle should always face away from the skin. The grip on the cannula will depend on the practitioners' preference, but care should be taken not to contaminate the sterile area.

Mode of Action: Disinfect the venipuncture site properly. • Locate an accessible and suitable peripheral vein visually and confirm by palpation. • Apply tourniquet. • After puncturing the vein with needle, confirm the successful venipuncture by visualizing blood in flashback chamber.

Residual Risk: There is no residual risk associated with the device, however preventive measures are considered in contraindication.

Instructions For Use:

- Step-1: • Select suitable size of Safety I.V. Cannula & inspect visually to ascertain that package is intact. • Wash hand with antiseptic solution and wear gloves. • Apply tourniquet. • Locate an accessible and suitable peripheral vein visually and confirm by palpation. • Disinfect the venipuncture site properly.
- Step-2: • Remove Safety I.V. Cannula from individual packaging. • Remove wing body clip upward.
- Step-3: • Remove needle cover by holding the wing body catheter hub of Safety I.V. Cannula and discard the needle cover. • Do not touch the catheter.
- Step-4: • Hold the Safety I.V. Cannula by Grip Pad keeping bevel face upward. • Puncture the vein with needle and confirm successful venipuncture by visualising blood in flashback chamber.
- Step-5: • Push the projection till catheter is adequately into the vein. • Stabilize the device at Projection with Index Finger. • Holding the Grip Pad, pull the needle gently until you hear a click sound, which confirms locking of the needle into the safety chamber.
- Step-6: • Remove tourniquet. • Hold the I.V. Cannula at wing body catheter hub. • Put digital pressure away from catheter tip. • Turn the Safety Chamber either left or right and remove from the wing body catheter hub. • Discard the safety chamber according to general hospital practice. • Connect the I.V. Infusion line. • 14 to 22 gauge catheters may be used with power injectors for which the maximum pressure setting is 300 psi/21bar.

Indications: • Infusion of I.V. Solution. • Intermittent intravenous drug administration. • To maintain hydration and/or correct dehydration if patient is unable to take sufficient volume of oral fluids. • The Safety IV Cannula can be connected with IV Set, BT Set, 3 way stop cock and without needle hypodermic syringe (device having 6 % conical fitting as per ISO 80369-7, ISO 80369-20).

Contraindications: • Safety I.V. Cannula should not be used on patient with known hypersensitivity to any of the materials employed.

Warnings: • The use of this product is restricted to a qualified doctor or a paramedic. • Read Instruction before use. • The product should be used according to the instructions for use. • The product should not be reprocessed. • Visually inspect and carefully check the damage of the device or packaging before use. • Improper transport and handling may cause structural and/or functional damage to device or packaging. • The product is guaranteed non-toxic, sterile & non-pyrogenic if the package has not been opened or damaged. • Do not clean or resterilise. For single use only. Discard after single use. • If the device is reused, than it may cause bacterial infection to the patient. • Store in cool & dry place. Do not expose to heat or direct sunlight. • The product should be used immediately after opening the packaging. • Paramedic must be trained in the practice of venipuncture and be aware of inherent risk.

Clinical Risk: • Thrombophlebitis at Insertion Site (Local Infection), it may occur if cannulation site not aseptic. • Cross-Puncture of vein and Local Extravasation of Blood, it may occur if re-insert the partially or/and completely withdrawn needle. • Failure of catheterization due to Blockage, if the device is reused. • Excessive pain during catheter insertion if multiple attempts at venipuncture site instead one due to untrained person. • Catheter pull out, it may occurs if re-insert the partially or/and completely withdrawn needle. • Bacteremia/Sepsis (Generalized Infection), it may occur if cannulation site not aseptic. • It may cause infection if product is used after expiry.

Caution: • Never try to reinsert the partially or completely withdrawn needle. • Change Safety I.V. Cannula according to hospital or institutional protocols. • The puncture site should be checked at regular intervals. • Safety I.V. Cannula should be remove in the event of local or systematic sign of infection. • Do not use scissors at or near insertion site. • Dispose off safely after use as per hospital or institutional protocols.

Note: If the above said caution are not followed by the Paramedic Staff, it can lead to halt the intended clinical benefits to patient.

Patient Population: • 22G-24G for Child, 14G-20G for Adult.

Safer Mode of Use: Up to 72 hrs. for best performance.

Clinical Benefits: Alleviation of disease by providing fluids/medicaments to the patients with channelling other compatible medical device.

Storage: Store in cool & dry place. Do not expose to heat or direct sunlight.

Incidents Report: In case of incidence Immediately inform to Manufacturer

(info@mediplusindia.com) and Competent authority of country.

MEDIPLUS (INDIA) LIMITED DISCLAIM ANY RESPONSIBILITY FOR POSSIBLE CONSEQUENCES RESULTING FROM IMPROPER USE.

Applicable Standards: ISO 10555-1, ISO 10555-5, ISO 15223-1 & ISO 13485.

REF	Catalogue number	Mfg. date with country of manufacture	Manufacturer
Use-by date	Do not use if package is damaged	Caution	
LOT	Batch code	STERILE EO Sterilized using ethylene oxide	Do not re-use
Do not resterilize	Consult instructions for use	Non-pyrogenic	
Single sterile barrier system	Product is not made with natural rubber latex	Does not contain DEHP	
MD	Medical Device	UDI Unique Device Identifier	Distributor
Importer	Keep away from sunlight	Keep dry	
EU REP	Authorised Representative in the European Union	CE mark European Conformity	AW/EFUS_71, Rev. 03 (Issued date: 26/11/2024)



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